1. 510(k) Summary

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	Sonendo, Inc.
DATE PREPARED:	December 4, 2013
CONTACT PERSON:	Dan W. Miller Sonendo, Inc. 26061 Merit Circle, Suite 101 Laguna Hills, CA 92653 Phone: (949) 766.3636 x544
TRADE NAME:	Sonendo OmniClean Endotherapy System
COMMON NAME:	Sonic Cleaning and Irrigation System
CLASSIFICATION NAME:	Ultrasonic Scaler
DEVICE CLASSIFICATION:	Class 2, per 21 CFR 872.4850
PRODUCT CODE	ELC
PREDICATE DEVICES:	Sonendo Endotherapy System (K130025) EMS Piezon Master 700 (K093000) Sonic Air MM 1500+ (MID) (K081268)

Substantially Equivalent To:
The Sonendo OmniClean Endotherapy System is substantially equivalent in intended use, principle of operation and technological characteristics to the Sonendo Endotherapy System (K130025), the EMS Piezon Master 700 (K093000) and the Sonic Air MM 1500+ (MID) (K081268).

Description of the Device Subject to Premarket Notification:
The Sonendo OmniClean Endotherapy System is a medical device intended to prepare, clean and irrigate 1st and 2nd molar teeth indicated for root canal therapy. The Sonendo OmniClean Endotherapy System is comprised of a Console, Foot Pedal and Molar Procedure Kit with a Handpiece.

Indication for Use:
The Sonendo OmniClean Endotherapy System is intended to prepare, clean and irrigate 1st and 2nd molar teeth indicated for root canal therapy.

Technical Characteristics:
The Sonendo OmniClean Endotherapy System has similar physical and technical characteristics to the predicate devices. These characteristics are tabulated below:

Characteristics	Sonendo OmniClean Endotherapy System (K133752)	Sonendo Endotherapy System (K130025)	EMS Piezon Master 700 (K093000)	Sonic Air MM 1500 + (MID) (K081268)
Function	Preparation, cleaning and irrigation of root canals	Preparation, cleaning and irrigation of root canals	Various, including preparation, cleaning and irrigation of root canals	Preparation, cleaning and irrigation of root canals
Principle of Operation	Generation of hydroacoustic waves and fluid motion. The tip of the device is placed inside the tooth during cleaning. Hydroacoustics are created by the water stream flowing through the guide tube and coming into contact with the fluid inside the tooth at the distal tip. The fluid stream is dispersed and deflected by the distal end plate of the tube creating hydrodynamics (fluid motion) within the tooth.	Generation of hydroacoustic waves and fluid motion. The tip of the device is placed inside the tooth during cleaning. Hydroacoustics are created by the water stream flowing through the guide tube and coming into contact with the fluid inside the tooth at the distal tip. The fluid stream is dispersed and deflected by the distal end plate of the tube creating hydrodynamics (fluid motion) within the tooth.	Generation of hydroacoustic waves and fluid motion	Generation of hydroacoustic waves and fluid motion
Treatment Site	Root canal	Root canal	Various, including Root canal	Root canal
Components	Control Unit Irrigation reservoirs Foot pedal Handpiece Accessories	Control Unit Irrigation reservoirs Foot pedal Handpiece Accessories	Control Unit Irrigation reservoirs Foot pedal Handpiece Instruments	Handpiece Instruments
Flow Rate	45 +/- 10 ml/min.	50-70 ml/min.	0-50 ml/min.	Unspecified.
Duration of Application	Leak test = 1 minute. Treatment time = 7 minutes and 45 seconds.	Leak test = 1 minute. Treatment time = 16 minutes.	Unspecified.	Unspecified.

Irrigation Fluid	NaOCl EDTA Water	NaOCL Water	NaOCL Water Chlorhexidine Hydrogen peroxide Citric acid	Water

Performance Data:
All necessary performance testing has been conducted for the Sonendo OmniClean Endotherapy System to assure substantial equivalence to the predicate devices and to demonstrate the devices perform as intended. All testing was performed on test units representative of finished devices. Testing included:

- Simulated Use
- EMC and Electrical Safety
- Thermal Safety
- Hydroacoustics
- Apical Extrusion and Pressure
- Cleaning

Basis for Determination of Substantial Equivalence:
Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the Sonendo OmniClean Endotherapy System is determined by Sonendo, Inc., to be substantially equivalent to existing legally marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 15, 2014

Sonendo, Incorporated
Mr. Dan Miller
Vice President of Regulatory, Clinical Affairs, and Quality Assurance
26061 Merit Circle, Suite 101
Laguna Hills, CA 92653

Re: K133752
Trade/Device Name: Sonendo OmniClean Endotherapy System
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: April 15, 2014
Received: April 18, 2014

Dear Mr. Miller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

6. Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K133752

Device Name: **Sonendo OmniClean Endotherapy System**

Indications for Use:

The Sonendo OmniClean Endotherapy System is intended to prepare, clean and irrigate 1st and 2nd molar teeth indicated for root canal therapy.

AND/OR

Prescription Use __X___
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use_____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
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